

UNITED STATE DEPARTMENT OF COMMERCE

Patent and Trademark Office

Address:

COMMISSIONER OF PATENTS AND TRADEMARKS

Washington, D.C. 20231

APPLICATION NO. FIRST NAMED INVENTOR ATTORNEY DOCKET NO. FILING DATE 09/160,977 09/25/98 SUNKARA S **EXAMINER** Г HM12/0524 HOECHST MARION ROUSSEL INC GOLDBERG, J 2110 EAST GALBRAITH ROAD ART UNIT PAPER NUMBER P 0 BOX 15300 CINCINNATI OH 45215-6300 1614 **DATE MAILED:** 05/24/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No. 09/160,977

Applicatit(s)

Sunkara

Examiner

Jerome D. Goldberg

Group Art Unit 1614



X Responsive to communication(s) filed on Apr 3, 2000	
☐ This action is FINAL .	
☐ Since this application is in condition for allowance except for formal in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D.	
A shortened statutory period for response to this action is set to expire is longer, from the mailing date of this communication. Failure to response application to become abandoned. (35 U.S.C. § 133). Extensions of 1 37 CFR 1.136(a).	ond within the period for response will cause the
Disposition of Claims	
X Claim(s) 1-12	is/are pending in the application.
Of the above, claim(s) 4, 5, 9, and 10	is/are withdrawn from consideration.
Claim(s)	is/are allowed.
X Claim(s) 1-3, 6-8, 11, and 12	is/are rejected.
☐ Claim(s)	
☐ Claims a	
Application Papers	
☐ See the attached Notice of Draftsperson's Patent Drawing Revie	w, PTO-948.
☐ The drawing(s) filed on is/are objected to b	by the Examiner.
☐ The proposed drawing correction, filed on	is bpproved disapproved.
\square The specification is objected to by the Examiner.	
\square The oath or declaration is objected to by the Examiner.	
Priority under 35 U.S.C. § 119	
Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).	
☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been	
received.	
☐ received in Application No. (Series Code/Serial Number)	
received in this national stage application from the International Bureau (PCT Rule 17.2(a)).	
*Certified copies not received:	
☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).	
Attachment(s)	
☑ Notice of References Cited, PTO-892	
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s).	
☐ Interview Summary, PTO-413	
☐ Notice of Draftsperson's Patent Drawing Review, PTO-948	
☐ Notice of Informal Patent Application, PTO-152	
SEE OFFICE ACTION ON THE FOLLOWING PAGES	

Art Unit: 1614

Claims 4, 5, 9 and 10 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non -elected invention. Election was made with traverse in Paper No. 4. Applicant's remarks are noted but the other synergistic combination will support separate patents. Applicant elected the synergistic combination of cytarabine and (E)-2'- deoxy-2'-fluoromethylidene cytidine with traverse in Paper No. 4. The claims are still being examined as they read on the elected invention.

Claims 1-3 and 8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the specific S-phase or M-phase specific agent" and "neoplastic disease state. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The term "a S-phase or M-phase specific agent" in claims 1-3 and 8 and "neoplastic disease state" in claims 1-3 and 8 lack clear exemplary support in the specification as filed.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, 6-8, 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over the McCarthy et al. reference of record taken with the Carter et al. reference of record.

Application/Control Number: 09/160,977 Page 3

Art Unit: 1614

The references disclose applicant's ingredients <u>alone</u> for treating cancer. In view of this, one skilled in the art would be motivated to combine two known anticancer agents for their additive effects. Claims directed to the combination with the synergistic propositions of record would overcome this rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Goldberg, whose telephone number is (703) 308-4606. The examiner can normally be reached on Monday through Friday from 9:00 a.m. to 3:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Cintins, can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

J. Goldberg:jmr

May 17, 2000

JEROME D. GOLDBERG PRIMARY EXAMINER GROUP 1200